

REMARKS

Claims 1 - 14 are pending in the present application. The Examiner provides a number of rejections and we list them here in the order in which they are addressed:

- I. Claims 2 - 5 and 9 - 11 are rejected under 35 U.S.C § 112 as allegedly lacking in specification support.
- II. Claims 1 - 14 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Dorman *et al.*, Toyosawa *et al.* or Coombes *et al.*.

I. The Claims Have Specification Support

The Examiner states that Claims 2-5 and 9-11 are rejected "Since the expression does not appear in the specification, as originally filed, nor is there a specific definition of the expression therein to define what it means." *Office Action*, pg. 3. The Applicants note that the Examiner has not particularly pointed out "the expression" but assume the reference is made to the term "controlled porosity". The Applicants disagree with the Examiner and point out the following support for this particular recitation; for example:

The microstructure of said pores can be **controlled** by varying the type of polymer, polymer concentration, inorganic compound content, quenching temperature, and solvent utilized. *Applicants' Specification*, pg 9 ln 4-6. [emphasis]

Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended the claims by removing the recitation of "controlled porosity"¹.

Applicants respectfully request the Examiner withdraw the rejection.

II. The Claims Are Not Obvious

The Examiner reasserts the references of Dorman, Toyosawa *et al.*, or Coombes *et al.* to reject Claims 1 - 14 under 35 U.S.C. § 103(a) as allegedly unpatentable. The Applicants

¹ Applicants note that the specification teaches that control (in part) is achieved by the ratio of reagents (see new Claims 15-23).

disagree and rebut the rejection on the basis that the Examiner has not provided a *prima facie* case of obviousness. Moreover, even if the references are (improperly) combined they do not teach the elements of the pending claims.

A. There Is No Basis To Combine The References

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference(s) themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991); and *MPEP* § 2142; Establishing A *Prima Facie* Case Of Obviousness. The Examiner is reminded that if ONLY ONE of the above requirements is not met, then a *prima facie* case of obviousness does not exist. In the present Office Action, the Applicants clearly demonstrate that the Examiner's rejection does not meet these criterion. The Applicants rebut the establishment of a *prima facie* case of obviousness by the argument below.

B. Even If (Improperly) Combined The References Do Not Teach The Polymers

The Examiner clarifies the previous rejection by stating that "What was intended by the examiner was that the Dorman and Coombes et al references would inherently have controlled porosity ... since they were making porous compositions from the claimed materials ...". *Office Action*, pg 2. The Examiner clearly has offered this only as a hypothesis since the statement lacks any evidentiary support since an inherency argument must be supported by teachings from the cited references, or other teachings from those skilled in the art.

The Examiner has not shown how the three cited references teach all the limitations of the claimed embodiment. The Applicants show below that none of the three cited references teach any polymer selected from the group consisting of poly(L-lactic acid), poly(D,L,-lactic acid-co-glycolic acid (PLGA) and poly(methyl methacrylate).

1. Dorman et al. Teaches Different Compounds

Dorman *et al.* discloses a composition wherein the primary component is an amino acid anhydride monomer:

Preferred are those α -amino acid N-carboxyanhydride monomer ... *Dorman et al.* col 3 ln 42-44.

One particular example, Example 10 discloses a hydroxyapatite-poly(γ -benzyl L-glutamate) polymer. Poly(L-lactic acid), poly(D,L-lactic acid-co-glycolic acid (PLGA) and poly(methyl methacrylate) are not mentioned in the *Dorman et al.* disclosure.

2. Toyosawa et al. Used A Different Polymer

Toyosawa et al. discloses a composition that is a copolymer rubber consisting essentially of ethylene and propylene. While there is a brief reference to polystyrene as a hydrating agent and glass powder as a "filler", *Toyosawa et al.* is silent on the primary polymers of poly(L-lactic acid), poly(D,L-lactic acid-co-glycolic acid (PLGA) and poly(methyl methacrylate). The Examiner is requested to note that the Applicant has removed polystyrene and glass powder from Claim 1 and Claim 6². This amendment is made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application. Applicants hereby expressly reserving the right to prosecute the original (or similar) claims.

3. Coombes et al. Teaches Away From Inorganic Compounds

Coombes et al. disclose a composition that may include either lactide homopolymers or polyglycolic acid (col 9 ln 1-17). However, at no point does *Coombes et al.* disclose a specific mixture of such polymers with hydroxyapatite or calcium phosphate. Further, hydroxyapatite and calcium phosphate are merely mentioned as possible "fillers". By contrast, the present specification teaches that the ratios of polymer and inorganic compound are used to control the desired outcome.

The Examiner is requested to note the addition of new claims 15-23 that exemplify specific embodiments of the preferred polymers in mixtures.

² It is believed that the amendment is unnecessary because the disclosure in *Toyosawa et al.*, with respect to polystyrene and glass powder, is in a different context. Nonetheless, the amendment simplifies the issues and furthers the prosecution at this time.

E. The References Do Not Disclose Simulated Body Fluid

The Examiner has not properly differentiated between the recited elements of independent Claim 1 and Claim 6 in the present invention. Applicants submit that the Examiner did not consider the element of "simulated body fluid" when including Claim 6 and the associated dependent claims within the 35 U.S.C. § 103(a) rejection. For the convenience of the Examiner, the Applicants provide below the definition of "simulated body fluid" set forth in the specification:

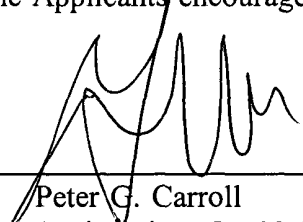
"Simulated Body Fluid" refers to a **man-made** aqueous solution comprising calcium and phosphorous ions at concentrations in a range between 0.5 - 2.5 times the concentration of said ions found in normal human plasma. For use in the present invention, it is preferred that elements in the simulated body fluid will not precipitate unless contact is made with a structure or surface. *Applicants' Specification, pg 5 ln 26-30. [emphasis added]*

Specifically, none of the references offered by the Examiner contemplate a composition that includes, or should include, a man-made aqueous solution comprising the elements of the definition presented above. The Applicants cannot find, and the Examiner has not pointed out, any disclosure of a simulated body fluid in the three cited references.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.252.3353.

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APPENDIX I
MARKED-UP VERSION OF REWRITTEN CLAIMS
PURSUANT TO 37 CFR § 1.121 (c)(1)(ii)

1. (Twice Amended) A composition, comprising:
 - i) a solid matrix having [a controlled] porosity that is substantially free of solvent comprising a mixture of;
 - a) at least one polymer, wherein said polymer is selected from the group consisting of poly(L-lactic acid), poly(D,L-lactic acid-co-glycolic acid (PLGA)[,] and poly(methyl methacrylate) [and polystyrene]; and
 - b) at least one inorganic compound wherein said inorganic compound is selected from the group consisting of hydroxyapatite[,] and calcium phosphate [and glass powder].
2. (Twice Amended) The composition of Claim 1, wherein said [controlled] porosity is greater than approximately 85%.
3. (Twice Amended) The composition of Claim 1, wherein said [controlled] porosity is greater than approximately 90%.
4. (Twice Amended) The composition of Claim 1, wherein said [controlled] porosity is greater than approximately 95%.
6. (Twice Amended) A composition, comprising:
 - a) a three dimensional structure formed by a solid matrix having a [controlled] porosity; and
 - b) a simulated body fluid contacting said structure, wherein said matrix comprises a mixture of;
 - i) at least one polymer, wherein said polymer is selected from the group consisting of poly(L-lactic acid), poly(D,L-lactic acid-co-

glycolic acid (PLGA)[,] and poly(methyl methacrylate) [and polystyrene]; and

- ii) at least one inorganic compound wherein said inorganic compound is selected from the group consisting of hydroxyapatite[,] and calcium phosphate [and glass powder].
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- 9. (Twice Amended) The composition of Claim 6, wherein said [controlled] porosity is greater than approximately 85%.
 - 10. (Twice Amended) The composition of Claim 6, wherein said [controlled] porosity is greater than approximately 90%.
 - 11. (Twice Amended) The composition of Claim 6, wherein said [controlled] porosity is greater than approximately 95%.
 - 13. (Twice Amended) The composition of Claim 1, wherein said [controlled] porosity is greater than approximately 80%.
 - 14. (Twice Amended) The composition of Claim 6, wherein said [controlled] porosity is greater than approximately 80%.